K111637

DEC - 6 2011

INNOVATION RADIANT 熱映光電
熱映光電股份有限公司
RADIANT INNOVATION Inc.,

[Attachment 2]

SPECIAL 510(K) SUMMARY

This Special 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:

1. **Submitter's Identification:**

Radiant Innovation Inc.,
1F, No.3 Industrial E. 9th Rd., Science-Based
Industrial Park, HsinChu, Taiwan

Contact:

Ms. LynnChen
QA Department Manager
Radiant Innovation Inc.
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Date Summary Prepared: May/13/2011

2. **Name of the Device:**

Infrared Ear Thermometer THP series
Classification Name: Thermometer, Electronic, Clinical
Regulation Number: 21 CFR 880.2910

3. **Predicate Device :**

Radiant Innovation Infrared Ear Thermometer, Models TH8 series (510(k)#: K011059).

4. **Device Description:**

The Radiant Innovation Inc., Infrared Ear Thermometer, Models THP series are electronic thermometers that use an infrared detector (thermopile detector) to detect body temperature using infrared radiation from the auditory canal. Its operation is based on measuring the natural infrared thermal radiation emanating from the tympanic membrane and the adjacent surfaces of the patient.

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To measure ear temperature, the ear thermometer is inserted into a patient's outer ear canal. A start button is pressed to start the measurement through the radiation exchanges. The electrical signal read out from the detector is amplified by hardware and processed by the microprocessor. The temperature from the auditory canal in the neonatal, pediatric and adult population used for intermittent monitoring of human body temperature in the home setting.

5. Intended Use:

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

6. Technological Characteristics and Substantial Equivalence:

Both the subject device (THP series) and the predicate device (TH8 series) have the same intended use as well as same fundamental technology. The comparison table showing the differences between the subject device (THP series) and the predicate device (TH8 series) is included in the 510(k) submission. The subject device (THP series) is substantially equivalent to the predicate device (TH8 series) since they have the same intended use, indications for use and similar technological characteristics.

The basic technological characteristics between subject device vs. predicate device.

Features	Predicate device(TH8 series)	Subject device (THP series)
510(k)#	K011059	K
Accuracy	35.5~42°C (95.9~107.6°F)+/-0.2°C (0.4°F), other +/-0.3°C (0.5°F).	
Temp. Range	34.0-42.2°C	
Ambient Range	10-40°C	
Response Time	1sec	
Read modes	Ear (Oral)	
Scale Selection	°C/°F	
Display Type	LCD	
Probe Cover	With	
Activation	Scan Button	Start Button
Memory	9 sets	25 set
Sensor Type	Thermopile	
Case	ABS	
Weight	70g	70g
Dimension (LxWxH)	14*3.8*3 cm	14.5*4*4.9 cm
Battery	3V Battery, CR2032 * 1	
2 Phase Battery Alarm	Yes	

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ASTM E1965-98 and EN12470-5:2003, as well as EN 60601-1 (IEC 60601-1) and EN 60601-1-2 (IEC 60601-1-2) requirements.

Guidance Documents included the FDA "*Guidance On The Content of Premarket Notification*

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(510(k)) Submissions for Clinical Electronic Thermometers", "*How to Prepare A Special 510(k)*", "*Deciding When to Submit a 510(k) for a Change to an Existing Device*".

8. Summary of Clinical Investigation:

According the clinical report, the repeatability of THP series are less than 0.3degC.
The result meets the criteria of EN12470-5 and ASTM 1965-98, so the THP series passes this clinical study.

9. Conclusions:

The RII Infrared Ear Thermometer THP series, have the same intended use and similar characteristics as the cleared device TH8 series. Moreover, bench testing contained in this submission supplied demonstrate that the modification of THP series do not raise any new questions of safety or effectiveness. Thus, the RII Infrared Ear Thermometer, Model THP series is substantially equivalent to the predicate device

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Lynn Chen
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Radiant Innovation Incorporated
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Re: K111637
Trade/Device Name: Radiant Innovation Inc. Infrared Thermometer THP Series
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: November 7, 2011
Received: November 8, 2011

Dear Ms. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111637

INNOVATION RADIANT 熱 映 光 電

熱映光電股份有限公司

RADIANT INNOVATION Inc.,

[Attachment 1]

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Radiant Innovation Inc. Infrared Ear Thermometer THP Series

Indications For Use:

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

Prescription Use _____ AND/OR Over-The-Counter Use ☒
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 12/6/11
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number K111637

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